INITIAL STATEMENT OF REASONS

California Code of Regulations, Title 22, Division 7, Chapter 10 – Health Facility Data

Article 7, CABG Data Reporting Requirements

Proposed Revisions Sections 97170 to 97198

PURPOSE AND RATIONALE OF THE PROPOSED REGULATORY ACTION

Health and Safety Code Section 128745 established the California Coronary Artery Bypass Graft (CABG) Outcomes Reporting Program (CCORP). The proposed regulatory amendments on CCORP have the following purposes:

a. To maintain data consistency among reporting hospitals by revising CCORP data elements to reflect changes in the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database
b. To improve the CCORP risk model by adding, changing and deleting the CCORP data elements based upon recommendations from the Clinical Advisory Panel (CAP)
c. To improve the CCORP hospital data reporting process by making minor program changes

By doing so, the proposed amendments would improve the data collection and public reporting efforts for CABG surgery in California. CCORP reports would better reflect the quality of care provided by California hospitals on CABG surgery.

<u>a. To maintain data consistency among reporting hospitals by revising CCORP data elements to reflect the changes in the STS Adult Cardiac Surgery Database</u>

CCORP is a mandatory data collection and reporting program for all hospitals performing CABG surgeries in California. The Office of Statewide Health Planning and Development (OSHPD) is charged with publishing risk-adjusted outcome reports at both the hospital and surgeon levels beginning with the January 2003 data collection.

California Code of Regulations (CCR) Section 97180 specifies that hospitals may use one of the three methods to collect the required data elements:

- The CCORP data collection tool
- A STS approved software vendor tool developed for collection of CCORP data, or
- Another data collection system which met the CCORP data requirements and format specifications

Of the 119 hospitals that reported to CCORP for the 2003 data period, 64 of them participated in the STS National Adult Cardiac Surgery Database and submitted CCORP data using the STS approved software. To reduce the administrative and data reporting burdens on hospitals, the majority of the CCORP data elements are STS data elements (STS version 2.41).

In 2004, STS modified some of its data elements and upgraded its approved software to version 2.52. This change resulted in six CCORP data elements being dropped or replaced, and 20 CCORP data elements being revised.

To maintain data consistency with STS, CCORP is proposing to revise its data elements to reflect the changes in STS 2.52. These changes were recommended by the CCORP CAP in its July 2004 and April 2005 meetings.

b. To improve the CCORP risk model by adding, changing and deleting the CCORP data elements based upon recommendations from the Clinical Advisory Panel

Section 128748 of the Health and Safety Code established a CAP to provide clinical consultation to CCORP. This is an appointed nine-member panel consists of surgeons, physicians and researchers. Upon recommendations from the CAP, OSHPD may add, delete, and revise CCORP data elements. The CAP had two meetings in 2004 and 2005 and recommended the revision of the isolated CABG surgery definition, addition of new CCORP data elements including complication outcomes and process measures, and deletion of data elements no longer collected by STS. These changes would improve the CCORP risk model to better reflect the surgery outcomes and quality of care provided by hospitals.

c. To improve the CCORP data collection process by making minor program changes

CCORP is proposing minor program changes to improve its data collection process. These changes include tightening the data acceptance criteria, providing more flexibility for hospitals to filing an extension, requesting hospitals to submit test files to improve data quality, and making clarifications to the Hospital and Surgeon Certification Forms. All these changes are intended to improve the data collection process and the quality of data submitted by hospitals.

CCR Section 97170

SPECIFIC PURPOSE OF THE REVISON
This proposed change clarifies the term ‘discharge’.

NECESSITY
This proposed change is necessary as CCORP data submission is based on the date of discharge.

CCR Section 97172

SPECIFIC PURPOSE OF THE REVISON
The proposed change provides a technical correction to the regulations. It provides the correct reference to CCR Section 97005 defining when a report is considered filed with OSHPD.

NECESSITY
The proposed change is necessary to provide a correct reference to help hospitals understand when a report is considered filed with OSHPD to avoid a penalty.

CCR Section 97174

SPECIFIC PURPOSE OF THE REVISON
The proposed revisions are intended to improve CCORP data quality by ensuring that all hospitals report the same data elements to CCORP, regardless of which data collection method they use or whether they participate in the STS National Adult Cardiac Surgery Database. The proposed amendments would align 20 CCORP data elements and exchange two CCORP data elements with STS 2.52. Changes also include the deletion of four data elements no longer collected by STS 2.52.

The proposed amendments are also intended to improve the CCORP risk model by updating the definition for isolated CABG surgery and adding new data elements used by STS in their risk model and inclusion of process measures. Changes also include addition of post-surgery complication outcome measures to the list of required data elements. All these changes would enrich the CCORP reports by providing a better reflection of quality of care given by hospitals and surgeons.

NECESSITY
The proposed changes are necessary for CCORP to provide hospital outcomes that truly reflect the quality of care and improved surgery techniques. These changes also reduce the administrative burden of STS hospitals by no longer requiring them to collect additional data not reported to STS and ensure that all CCORP hospitals are reporting the same data elements.

CCR Section 97178

SPECIFIC PURPOSE OF THE REVISON

The proposed change would provide more flexibility for hospitals to file an extension. It eliminates the three extension filing limit on hospitals per reporting period. Hospitals that cannot meet a reporting deadline could fully use up their 30 extension days, regardless of the number of extensions they filed.

NECESSITY
The proposed change is necessary to provide hospitals that cannot meet the reporting deadline with an extension of up to 30 days. Current regulations specify that hospitals could file a maximum of three extensions for up to 30 days per reporting period. There are instances that hospitals with unused extension days cannot request an extension because they have already filed three extensions for that reporting period.

CCR Section 97180

SPECIFIC PURPOSE OF THE REVISON
The proposed change would improve data quality by requiring hospitals not using the CCORP data collection tool to submit a test file to OSHPD, when certain conditions are met. It allows OSHPD staff time to work with hospitals before their data is due to avoid any subsequent data rejection and time-consuming data corrections. It ensures that hospitals data meet CCORP requirements and are submitted in a timely manner.

NECESSITY
The proposed change is necessary to provide OSHPD with good quality data in a timely manner for the development of the annual hospital reports and bi-annual surgeon reports. Currently, hospitals are not mandated to submit a test file to CCORP. This may result in hospitals having multiple data rejections and time-consuming data corrections after the reporting deadline. This in turn delays our data cleaning process and can prevent OSHPD from publishing timely reports.

CCR Section 97184

SPECIFIC PURPOSE OF THE REVISON
The proposed changes clarify the paperwork requirements for submitting CCORP data. Hospitals must submit a signed and complete Hospital Certification Form with the report. Surgeon Certification Forms, if applicable, also need to be signed and completed.

NECESSITY
The proposed changes are necessary to inform hospitals that Hospital and Surgeon Certification Forms submitted with the report have to be completed and signed. This prevents unnecessary data rejection due to paperwork problems.

CCR Section 97188

SPECIFIC PURPOSE OF THE REVISON
The proposed changes clarify the paperwork requirements for submitting CCORP data. Surgeon's name and license number provided on the Surgeon Certification Form (OSH-CCORP 415) (Revised 05-05) must be the same as in the submitted hospital data and match the California Medical Board licensing information. In addition, the changes specify that surgeons who do not complete the Surgeon Certification Form (OSH-CCORP 415) (Revised 05-05) must provide the number of cases reported in the hospital data on the Hospital Certification Form (OSH-CCORP 416) (Revised 05-05).

NECESSITY
The proposed changes are necessary to help hospitals complete the Surgeon Certification Form (OSH-CCORP 415) (Revised 05-05) to avoid unnecessary data rejection due to paperwork problems. It also prevents discrepancies among surgeon information in the data file, on the Surgeon Certification Form and in the California Medical Board database. Currently, hospitals need to correct such discrepancies after data are accepted. Correcting the problem earlier on will speed up the data correction process.

CCR Section 97190

SPECIFIC PURPOSE OF THE REVISON
The proposed changes specify minor revisions to the Hospital Certification Form (OSH-CCORP 416) (Revised 05-05). They add the name of vendor to the form if the hospital is using a STS data collection tool. Changes also clarify that the Surgeon Certification Form (OSH-CCORP 415) (Revised 05-05) submitted with the report has to be signed and completed. Changes require that the surgeon's name and license number provided on the Hospital Certification Form (OSH-CCORP 416) (Revised 05-05) be the same as in the submitted hospital data and match the California Medical Board licensing information. Finally, hospitals must provide the number of cases reported for each surgeon on the Hospital Certification Form (OSH-CCORP 416)(Revised 05-05) for surgeons who did not complete their own Surgeon Certification Form (OSH-CCORP 415)(Revised 05-05).

NECESSITY
The proposed change to request STS vendor information is necessary because data problems are mostly vendor-specific. Knowing which STS vendor was used in data submission helps OSHPD staff work with hospitals in data correction. The other proposed changes help hospitals complete the Hospital Certification Form (OSH-CCORP 416) (Revised 05-05) to avoid unnecessary data rejection and speed up the data correction process.

CCR Section 97198

SPECIFIC PURPOSE OF THE REVISON
The proposed change clarifies that a hospital is not considered delinquent if an extension request was granted by OSHPD. Such hospital will not receive a penalty assessment.

NECESSITY
The proposed change is necessary to clarify the circumstances under which OSHPD will assess a penalty.

ALTERNATIVES CONSIDERED/EFFECT ON SMALL BUSINESS

OSHPD considered but found no reasonable alternative to the proposed regulatory action. It is important that all hospitals report the same data elements to CCORP. It is therefore necessary to revise the CCORP data elements to reflect the changes in STS 2.52. In addition, to truly reflect the quality of CABG surgery, it is important that our report reflects the latest research findings and changes in surgery care, and expand outcomes to include complications.

CCORP held a stakeholder meeting on January 27, 2005 to collect input from CCORP hospitals about the proposed changes. Thirty hospitals participated in the meeting and provided valuable input to the proposed regulatory action. As a result, two proposed complication outcomes and four proposed new STS data elements were dropped due to perceptions of low validity.

Hospitals required to report to CCORP are not considered small businesses; the proposed regulatory action therefore does not affect small businesses.

DETERMINATION OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

OSHPD has determined that the proposed regulatory action will not have a significant adverse impact on business. The estimated cost for a non-STS CCORP hospital to comply with the proposed regulatory action is $1,151 per year. For STS hospitals, there is no additional cost incurred. Indeed, the proposed changes would reduce the administrative burden of these hospitals. Non-STS hospitals which participated in the January 2005 Stakeholder Meeting also welcomed these changes as they will better reflect the quality of care in their hospitals.

LIST OF MATERIALS RELIED UPON IN THE PROPOSED ACTION

Administrative Documents

- CCORP Clinical Advisory Panel July 26, 2004 Meeting Minutes
- CCORP Clinical Advisory Panel April 27, 2005 Meeting Minutes
- CCORP Stakeholder Meeting January 27, 2005 Meeting Minutes
- California Employment Development Department, Labor Market Information Division, Occupational Employment Statistics Survey 2004.
- New York State Department of Health. Cardiac Surgery Report, Adult. Instructions and Data Element Definitions. January 2004.
- STS Adult Cardiac Database, Version 2.52 Data Specifications
- STS Risk Modeling Variables

Publications

- Bureau of Labor Statistics, Employer Costs for Employee Compensation – December 2004.
- Mass-DAC Department of Health Care Policy Harvard Medical School. October 2004. *Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts. January 1 – December 31, 2002.*
- New York State Department of Health. 2004. *Adult Cardiac Surgery in New York State, 2000-2002*
- New Jersey Department of Health and Senior Services. November 2004. *Cardiac Surgery in New Jersey 2001. A Consumer Report.*
- Pennsylvania Health Care Cost Containment Council. March 2005. *Pennsylvania's Guide to Coronary Artery Bypass Graft Surgery 2003.*